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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,840	07/25/2001	Robin Arthur Ellis Carr	PU3565USW	7700

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/16/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/806,840

Applicant(s)

Carr et al

Examiner
Maurie G. Baker, Ph.D.

Art Unit
1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 17, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 14-16, 24-26, and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-23, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: notice to comply

DETAILED ACTION

1. The Responses filed March 14, 2003 and July 17, 2003 (Papers No. 11 & 14) are acknowledged. Claims 32-47, 50 and 51 were cancelled, and no claims were amended or added. Therefore, claims 1-31 are pending.

Election/Restriction

2. Applicant's election without traverse of Group I (claims 1-31) is acknowledged. The election of species of the chemical construct of Example 1 and the clarification thereof in Paper No. 14 is also noted.

3. Claims 14-16, 24-26 and 28-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic claim.

4. Please note the following with respect to the species election, see MPEP § 803.02:

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Therefore, claims 1-13, 17-23 and 27 are under examination.

Specification

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. *See, for example, instant specification page 4, line 24.*

Note that the lengthy specification has not been checked to the extent necessary to determine if the above is inclusive of all sequences therein. Applicant's cooperation is requested in placing all sequences in the specification in compliance.

Claim Objections

7. Claim 1 is objected to because of the following informalities: The claim contains non-elected subject matter as it is not limited to a "chemical construct" where the fragment Fr contains "a means for imparting a characteristic signature to the mass spectrum of the fragment". See also paragraph 11B below. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-13, 17-23 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a "chemical construct" that is defined in a completely functional manner (i.e. claim 1). There are a wide variety of compounds that could meet the functional limitations of the claim encompassing different entities of widely varying structures. It is noted that some of the dependent claims define portions of the structure of such constructs, but none of the claims describe the construct with particularity. The instant specification provides only very limited examples of such "chemical constructs".

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled

in the art to visualize or recognize the identity of the subject matter purportedly described.

Adequate disclosure, like enablement, requires representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. The more unpredictable the art the greater the showing required (e.g. by “representative examples”) for both enablement and adequate disclosure. A representative number of examples means that the species that are adequately described are representative of the entire genus. When there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Therefore it is deemed that the instant specification lacks adequate support relating to the genus of claimed “chemical construct”. It is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned in the context of the claimed invention. This further evidences that instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-13, 17-23 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. Claim 1 (and all claims dependent thereon) is indefinite because the phrase “characterized in that cleavage of the skeleton of the construct forms or introduces on the chemical fragment Fr at the first cleavage site a moiety comprising sensitising group G which sensitises the chemical fragment Fr to instrumental, e.g. mass spectroscopic, analysis” is unclear and highly confusing. It appears that this limitation is a process limitation and a product is being claimed. Moreover, it is unclear how this limitation limits the claimed product as it is merely describing a *possible* reaction that the product could undergo (i.e. “cleavage of the skeleton of the construct”) and not a portion of the product itself. Additionally, it appears that this may also be merely describing a property of the construct (its ability to be cleaved and the product that is formed when cleaved).
- B. Claim 1 (and all claims dependent thereon) as well as claims 11, 22 and 27 recite the phrases “e.g.”, “for example”, “such as” and “particularly”. These phrases render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- C. Claims 2 and 7 (and all claims dependent thereon) are indefinite as it is unclear how the “means for imparting a characteristic signature to the mass spectrum of the fragment” is different from the sensitising group of

claim 1. A “means for imparting a characteristic signature to the mass spectrum of the fragment” could also be a moiety that sensitizes the chemical fragment to instrumental, e.g. mass spectroscopic, analysis. Moreover, in claim 7, the recitation of “the spacer group A containing a means for imparting a characteristic signature to the mass spectrum of the fragment” is additionally confusing as it is not clear what the relationship of the spacer group A and the connecting group Y is, as well as the specifics of what is meant by the term “containing”. It appears that the claims are incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

- D. Claim 9 (and all claims dependent thereon) is confusing as the second nitrogen in the group A is shown to have three substituents already (i.e. Alk-NH-X¹). Thus it is unclear how this group could also be attached to L² as required.
- E. Claim 18 (and all claims dependent thereon) lacks antecedent basis for the alkylene diamine group recited in the claim. Also, similar to C above, it appears that the claim is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1, 2, 5-8, 10-13, 21-23 and 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carrasco et al (Tet. Lett. 1997; on PTO-1449).

Note that the claims are quite unclear due to the many issues under 35 U.S.C. 112, second paragraph. The claims have been broadly interpreted to the best of the examiners ability in the formation of this rejection as described in detail below.

Carrasco et al disclose “resin-bound constructs” having a linker with two different cleavage sites attached thereto. See, for example, Figure 1 of the reference. The constructs of Carrasco et al contain a “desired organic substrate” reading on R and an “ionization sequence” (see Figure 1, Scheme 1 and Abstract). The “derivatized resin” of Carrasco et al incorporates a “dual linker strategy” where the “combination of the photocleavable linker and the ionization tag enables direct analysis of the beads by MALDI-MS” (reading on the claimed Fr group comprising a “sensitising group G” and/or a “means for imparting a characteristic signature to the mass spectrum of the fragment”). The two linkers of the reference are separated by a spacer group (i.e. ionization sequence), reading on instant claims 5-8. The ionization sequence of Carrasco et al has a quaternized primary amine therein, reading on instant claims 10-13. The two linkers of Carrasco et al are photocleavable and chemically (acid) cleavable, respectively, reading on instant claims 22-23 and 27.

In the alternative, although Carrasco et al does not specifically disclose that cleavage “of the skeleton of the construct forms or introduces on the chemical fragment Fr at the first cleavage site a moiety comprising sensitising group G which sensitises the chemical fragment Fr to instrumental, e.g. mass spectroscopic, analysis”, such would be obvious to one of ordinary skill as the

construct of Carrasco et al has the exact same structure as claimed. Note that “[p]roducts of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

Also, the construct of Carrasco et al meets all of the limitations of the construct of the instant claims except for the product-by-process limitations (see paragraph 11A above) and would either anticipate or render obvious the claimed construct. “[E]ven though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The examiner respectfully points out that since all of the claims are drawn to a “chemical construct”, but this product is defined as a product-by-process, that any “construct” that reads on this product anticipates the claims. The process by which the claimed construct is reacted does not appear to lend patentable weight to the claimed invention.

Status of Claims/Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
October 8, 2003



MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: _____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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